K011030

C. 510(k) SUMMARY OF SAFETY AND EFFECTIVENESS
[in Accordance with SMDA of 1990]

MAR 1 2002

Miethke Shunt System

January 22, 2001

COMPANY: Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, PA 18034

Establishment Registration Number: 2916714

CONTACT: Joyce Thomas, Director Regulatory Affairs & Quality Assurance
800/258-1946 x 5076 (phone)
610/231-3713 (fax)

TRADE NAME: Aesculap® - Miethke Shunt System

COMMON NAME: Hydrocephalus Shunt System

DEVICE CLASS: Class II

PRODUCT CODE: JXG

CLASSIFICATION: 21 CFR Section 882.5550: Central Nervous System fluid shunt and components.

REVIEW PANEL: Neurology

INDICATIONS FOR USE

The Miethke Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

DEVICE DESCRIPTION

The components of the Miethke Shunt System can include the DualSwitch®-Valve, a proximal diaphragm valve. The DualSwitch®-Valve consists of two chambers and is available in nine different pressure ranges.

The Paedi-Gav-Valve is a "ball-in-cone" valve in line with a gravitational valve and is available in six pressure ranges and with various accessory configurations.

The MonoStep®-Valve belongs to the group of diaphragm valves but the valve seat is designed as a "ball-in-cone-breech". It is manufactured from titanium and is available in 5 different ranges as a single device as well as a complete shunt system in different configurations.

The ShuntAssistant® is manufactured from titanium also and is used to control overdrainage. The ShuntAssistant® should be implanted with an adjustable or conventional differential pressure valve like the MonoStep®-Valve. The ShuntAssistant® is available in 5 different pressures ranges. A pediatric ShuntAssistant® (Paedi-/ShuntAssistant) is also available.

Various accessories such as catheters, connectors, deflectors and reservoirs are also included within the Shunt System.

PURPOSE FOR SUBMISSION

The purpose for this submission is to gain marketing clearance for the Miethke Shunt System.

PERFORMANCE DATA

No applicable performance standards have been promulgated under Section 514 of the Food, Drug and Cosmetic Act for this device system

SUBSTANTIAL EQUIVALENCE

Aesculap®, Inc. believes that the Aesculap® Miethke Shunt System is essentially identical to the J & J Hakim Micro Programmable Valve System (K980778), Heyer-Schulte Novus (K9618590, P/S Medtronic Button (K911410), P/S Medtronic Delta (K902783), Heyer-Schulte Spetzler LP Shunt (K871685), Cordis NMT Gravity Compensating Accessory (K932429) and the Cordis NMT Hakim Standard/Pediatric Valves (K861377).

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
9200 Corporate Boulevard
Rockville MD 20850

MAR 1 2002

Ms. Joyce Thomas
Director, Regulatory Affairs
and Quality Assurance
Aesculap®, Inc.
3773 Corporate Parkway
Center Valley, Pennsylvania 18034

Re: K011030
Trade/Device Name: Miethke Shunt System
Regulation Number: 882.5550
Regulation Name: Central nervous system fluid shunt and components
Regulatory Class: II
Product Code: JXG
Dated: February 14, 2002
Received: February 15, 2002

Dear Ms. Thomas:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration.

If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to such additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

This letter will allow you to begin marketing your device as described in your Section 510(k) premarket notification. The FDA finding of substantial equivalence of your device to a legally marketed predicate device results in a classification for your device and thus, permits your device to proceed to the market.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801 and additionally 21 CFR Part 809.10 for in vitro diagnostic devices), please contact the Office of Compliance at (301) 594-4659. Additionally, for questions on the promotion and advertising of your device, please contact the Office of Compliance at (301) 594-4639. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). Other general information on your responsibilities under the Act may be obtained from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 443-6597 or at its Internet address http://www.fda.gov/cdrh/dsma/dsmamain.html

Sincerely yours,

for Mark N. Melkerson

Celia M. Witten, Ph.D., M.D.
Director
Division of General, Restorative
and Neurological Devices
Office of Device Evaluation
Center for Devices and
Radiological Health

Enclosure

B. INDICATIONS FOR USE STATEMENT

510(k) Number: K011030

Device Name: **Miethke Shunt System**

Indication for Use:

The Miethke Shunt System is intended to shunt cerebrospinal fluid (CSF) from the lateral ventricles of the brain into the peritoneum.

(PLEASE DO NOT WRITE BELOW THIS LINE - CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of Device Evaluation (ODE)

Prescription Use ✓ or Over-the-Counter Use _____

(per 21 CFR 801.109)

(Optional Format 3-10-98)

(Division Sign-Off)
Division of General, Restorative
and Neurological Devices

510(k) Number K011030